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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael A. Martinelli, Brad Jascob and Mark W. Hunter
Title: Patient-Shielding And Coil System
Docket Number: 56300- (MRT-21)

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

Sir

TRANSMITTAL LETTER

Enclosed herewith for filing in the above-identified patent application please find the following listed items:

1. Application and a check in the amount of $380.00 to cover the cost of the requisite fee;
2. Declaration Petition and Power of Attorney (Unexecuted);
3. Eight (8) Sheets of Informal Drawings;
4. Patent Application Transmittal Letter; and
5. Return Postcard.

In connection with the foregoing matter, please charge any additional fees which may be due, or credit any overpayment, to Deposit Account Number 50-1133. A duplicate copy of this letter is provided for this purpose.

Respectfully submitted,

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CERTIFICATE OF MAILING

"**Express Mail**" Mailing Label Number EL517536922US Date of Deposit October 27, 2000

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Box Patent Application, Assistant Commissioner for Patents, Washington, DC 20231.

Cynthia Joseph
(Person Mailing)

(Signature)

PATENT APPLICATION TRANSMITTAL LETTER
(Small Entity)

Docket No.
56300- (MRT-21)

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

Michael A. Martinelli, Brad Jascob and Mark W. Hunter

For: **PATIENT-SHIELDING AND COIL SYSTEM**

Enclosed are:

- ☒ Certificate of Mailing with Express Mail Mailing Label No. **EL517536922**
- ☒ **Eight (8) (Informal)** sheets of drawings.
- ☐ A certified copy of a application.
- ☒ Declaration ☐ Signed. ☒ Unsigned.
- ☒ Power of Attorney
- ☐ Information Disclosure Statement
- ☐ Preliminary Amendment
- ☐ Verified Statement(s) to Establish Small Entity Status Under 37 C.F.R. 1.9 and 1.27.
- ☐ Other:

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	5	- 20 =	0	x $9.00	$0.00
Indep. Claims	1	- 3 =	0	x $40.00	$0.00
Multiple Dependent Claims (check if applicable) ☐					$0.00
				BASIC FEE	$355.00
				TOTAL FILING FEE	$355.00

- ☒ A check in the amount of **$380.00** to cover the filing fee is enclosed.
- ☐ The Commissioner is hereby authorized to charge and credit Deposit Account No. **50-1133** as described below. A duplicate copy of this sheet is enclosed.
  - ☐ Charge the amount of as filing fee.
  - ☒ Credit any overpayment.
  - ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
  - ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **October 27, 2000**

Signature

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MRTK-021

APPLICATION

FOR

UNITED STATES LETTERS PATENT

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Michael A. Martinelli, a U.S. citizen, residing in Winchester, MA, has invented certain improvements in a PATIENT-SHIELDING AND COIL SYSTEM of which the following description in connection with the accompanying drawings is a specification, like reference characters on the drawings indicating like parts in the several figures.

PATIENT-SHIELDING AND COIL SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

The following United States patent applications, which were concurrently filed with this one on October 28, 1999, are fully incorporated herein by reference: Method and System for Navigating a Catheter Probe in the Presence of Field-influencing Objects, by Michael Martinelli, Paul Kessman and Brad Jascob, Serial Number 60/161,991; Coil Structures and Methods for Generating Magnetic Fields, by Brad Jascob, Paul Kessman and Michael Martinelli, Serial Number 60/161,990; Navigation Information Overlay onto Ultrasound Imagery, by Paul Kessman, Troy Holsing and Jason Trobaugh, Serial Number _____; Registration of Human Anatomy Integrated for Electromagnetic Localization, by Mark W. Hunter and Paul Kessman, Serial Number 09/429,569; System for Translation of Electromagnetic and Optical Localization Systems, by Mark W. Hunter and Paul Kessman, Serial Number 09/429,568; Surgical Communication and Power System, by Mark W. Hunter, Paul Kessman and Brad Jascob, Serial Number 09/428,722; and Surgical Sensor, by Mark W. Hunter, Sheri McCoid and Paul Kessman, Serial Number 09/428,721.

This application claims the benefit of United States Provisional Application Number 60/161,989, filed October 28, 1999, the contents of which are incorporated herein by reference in their entirety, and from which priority is claimed.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

REFERENCE TO MICROFICHE APPENDIX

Not Applicable

BACKGROUND OF THE INVENTION

The present invention relates to, a patient-shielding system for use when a patient is exposed to capacitive currents as a result of immersion into a time-varying magnetic field. More particularly, this invention relates to a system for redirecting potentially harmful currents away from organs such as the heart when a medical procedure includes exposing that organ to a time-varying magnetic field.

Systems and methods for determining the position and orientation of surgical probes based on the use of magnetic fields are known. See, for example, U.S. Patent 5,592,939. Such systems and methods generally rely on the presence of a time varying magnetic field in the surgical region of interest. An exemplary navigation system is shown in FIG. 1. The exemplary system of FIG. 1 contains platform 10 in which is embedded coils for generating a time-varying magnetic field. Two such coils are depicted as first coil set 12 and second coil set 14. Field line 22 depicts the orientation of a magnetic field amplitude at an instant of time. See also U.S. Patent 5,592,939.

Present techniques for projecting a time varying magnetic field into a surgical region of interest preferably position the patient proximal to the coils that are generating the necessary fields. This is depicted in FIG. 2. Patient 24 is generally kept from direct contact with coil sets 12 and 14 by non-conducting layer 20. As a result of this relationship, there are times when coil sets 12 and 14, located proximally to the surgical region of interest, may have differing voltage potentials. By way of example only, in FIG. 2, coil set 12 is at positive potential 16, and coil set 14 is at negative potential 18. A uniform amplitude field that has its major component lateral to a plane determined by an operating room table is thus generated by two coils at different voltage potentials separated along that lateral dimension. Field line 22 in FIG.2 indicates the direction of such an amplitude. In the relationship indicated in FIG. 2, the surgical region of interest has loop characteristics of what is known as a capacitive current. A schematic of such a current is depicted in FIG. 3. For a time-varying magnetic field where the frequency is of the order of $f = 20$ kilohertz and the difference between positive potential 16 and negative potential 18 is $V = 25$ volts, capacitive current 34, denoted by I, can exceed what is considered desirable. For example, typical safety standards, such as those of Underwriter Laboratories, require that the current through a patient be less than $I = 10$ microamps. For

insulating layer 20 with capacitance 30 of the order of $C = 10^{-10}$ farads, and where patient 24 has a resistance 32 of approximately 100 ohms, capacitive current 34 is of the order

$$I = V(2\pi fC) = 345 \text{ microamps}$$

This is well in excess of a 10 microamp current.

In light of the foregoing, it is desirable to reduce the magnitude of the capacitive current introduced by a magnetic field coil within a surgical region. It is an object of the present invention to substantially overcome the above-identified disadvantages and drawbacks of the prior art.

SUMMARY OF THE INVENTION

The foregoing and other objects are achieved by the invention which in one aspect comprises a patient-shielding and coil system, including a coil wire electrically coupled to a source of electrical current, an electrically conductive surface, insulation material situated between the coil wire and the conductive surface, and a drain wire connected to the conductive surface and forming a capacitive current loop with respect to the source.

In another embodiment of the invention, the conductive surface has a resistance of substantially 1 ohm per square.

In another embodiment of the invention, the electrically conductive surface forms an incomplete enclosure of the coil wire, so as to create an incomplete electrical circuit.

In another embodiment of the invention, the conductive surface includes an upper portion and a lower portion.

In another embodiment of the invention, the conductive surface includes a polyester foil, vapor deposited with aluminum.

BRIEF DESCRIPTION OF DRAWINGS

The foregoing and other objects of this invention, the various features thereof, as well as the invention itself, may be more fully understood from the following description, when read together with the accompanying drawings in which:

FIG. 1 depicts an exemplary coil system for generating a uniform amplitude magnetic field for a navigational system.

FIG. 2 depicts an effect the exemplary system of FIG. 1 can have on a patient.

FIG. 3 is a circuit diagram of a capacitive current loop formed by the configuration of FIG. 2.

FIG. 4 depicts an exemplary patient-shielding and coil system consistent with the present invention.

FIG. 5 depicts a cross section of a portion of the exemplary system of FIG. 4.

FIG. 6 depicts an example of how current flows across a cross section of the exemplary system of FIG. 4.

FIG. 7 depicts an alternative exemplary patient-shielding and coil system consistent with the present invention.

FIG. 8 depicts a side view of the exemplary patient-shielding and coil system of FIG. 7.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a system for redirecting potentially harmful currents away from organs such as the heart when a medical procedure includes exposing that organ to a time-varying magnetic field.

FIG. 4 depicts a patient-shielding and coil system in accordance with a preferred embodiment of the present invention. The ends of coil wire 44 are attached to a driving voltage source (not shown). Between the ends of coil wire 44 and the coil assembly 40, coil wire 44 is wrapped about itself as twisted pair 47. Within coil assembly 40, coil wire 44 is looped N times. The current along coil wire 40 is denoted I_M. Thus, in the absence of any other effects, the net current around coil assembly 40 is NI_M.

Also depicted in FIG. 4 is coil form 54. Coil form 54 surrounds that portion of coil wire 44 where coil wire 44 is looped N times. Coil form 54 is depicted in FIG. 4 as rectangular in shape, but other shapes such can be used as well, and are consistent with the present invention. Other embodiments of the invention may include a coil wire 44 without a coil form, such that the coil wire is looped without the benefit of any coil form.

Also depicted in FIG. 4 is drain wire 42 and shield 52, depicted as the dashed line. The shield 52 is preferably electrically conductive, so as to support an electrical current in the presence of a voltage potential. In some embodiments, the shield 52 may include a non-conductive foundation bonded, or otherwise attached, to a conductive surface. Drain wire 42 is attached, or otherwise mounted, to shield 52. Shield 52 extends along twisted pair 47 and envelops most of coil form 54, and thus envelopes most of coil wire 44. However, shield 52 does not form a complete enclosure around coil axis 45, so as to prevent a compensating current from forming along the surface of shield 52 that would serve to decrease the magnitude of the magnetic field produced by the coil assembly 40. Thus, shield 52 ends at gap 46.

A more detailed cross section of coil assembly 40 consistent with a preferred embodiment of the present invention is shown in FIG. 5. Shield 52 is exterior of coil form 54. The lower portion of shield 52 is depicted as "U" shaped, and the upper portion of shield 52 is depicted as a cover. The lower and upper portions of shield 52 can preferably be connected by conductive silver ink at location 56, but other techniques of connectivity using any type of conducting material can also be used. Shield 52 can be composed of a polyester foil with aluminum vapor-deposited on its surface, but other compositions with the resistance discussed below can also be used. The resistance of the vapor-deposited aluminum, a thin film, used in one embodiment of the present invention is of the order 1 ohm per square. The unit "ohm per square" is a unit of resistance known in the art appropriate for discussions of thin film material. Drain wire 42 is connected to shield 52 and is connected to ground. Drain wire 42 carries the current I_C along the length of shield 52. At each point along shield 52 the current I_C in drain wire 42 is the total of all current induced between that point and gap 46. Because of the ground connection, these are capacitive currents as discussed above with regard to patient 24. However, here the capacitive current loop is closed with respect to a ground rather than through patient 24. The current I_C, at an instant of time, is associated with positive potential 16 and the capacitance of coil form 54, where the current loop of interest is completed by shield 52 connected to ground via drain wire 42.

Also depicted in the cross section shown in FIG. 5 are the N cross sections of coil wire 44 contained within coil form 54. Because of the presence of current I_C along drain wire 42, the

current in coil wire 44 is altered by an amount of the order $I_C/(2N)$. This is depicted in FIG. 6 where drain wire 42 along shield 52 has a current $-I_C/2$ and coil wire 44 along one loop has an adjusted current $I_M + I_C/(2N)$. The net current including the effect of N loops of coil wire 44 and drain wire 42 along coil assembly 40, however, remains the value as before NI_M. The current along drain wire 42 is cancelled. The net result is that patient 24 is shielded from capacitive current 34 by an amount of the order I_C. Nevertheless, the desired magnetic fields for navigation throughout the surgical region of interest remain the same.

FIGS. 7 and 8 depict a patient-shielding and coil system in accordance with another preferred embodiment of the present invention. In FIGS. 7 and 8, shield system 70 is placed over platform 10 containing coil sets 12 and 14. Shield system 70 is depicted as containing vapor-deposited conductive film 76 on top of non-conductive plastic sheet 74. Conductive film 76 is connected to drain wire 42. Coil sets 12 and 14 are connected in series and are driven through twisted pair 47 to produced the desired magnetic fields. Positive potential 16 and negative potential 18 are shielded from patient 24 the conductive film 76. Vapor-deposited conductive film 76 has a resistance of the order 1 ohm per square. This resistance is sufficient to produce little effect on the magnetic fields, indicated in FIG. 8 by field lines 48. Nevertheless, this resistance is sufficient to protect patient 24 from capacitive current 34.

Experiments performed to measure the effect on navigation of the currents induced in the shield system 70 indicate that these currents are small and have an effect of less than 0.1% on navigation accuracy. The small residual effect can be eliminated by a calibration of the navigating fields in the presence of shield system 70.

Systems consistent with the present invention shield a patient from capacitive currents that arise as a result of patient immersion into a time-varying magnetic field. The foregoing description of implementations of the invention has been presented for purposes of illustration and description. It is not exhaustive and does not limit the invention to the precise form disclosed. Modifications and variations are possible in light of the above teachings or may be acquired from practicing the invention.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be

considered in respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of the equivalency of the claims are therefore intended to be embraced therein.

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What is claimed is:

1. A patient-shielding and coil system, comprising:

a coil wire electrically coupled to a source of electrical current;

an electrically conductive surface;

insulation material situated between the coil wire and the conductive surface; and

a drain wire connected to the conductive surface and forming a capacitive current loop with respect to the source.

2. A system according to claim 1, wherein the conductive surface has a resistance of substantially 1 ohm per square.

3. A system according to claim 1, wherein the electrically conductive surface forms an incomplete enclosure of the coil wire, so as to create an incomplete electrical circuit.

4. A system according to claim 1, wherein the conductive surface includes an upper portion and a lower portion.

5. A system according to claim 1, wherein the conductive surface includes a polyester foil, vapor deposited with aluminum.

ABSTRACT

A patient-shielding and coil system, including a coil wire electrically coupled to a source of electrical current, an electrically conductive surface, insulation material situated between the coil wire and the conductive surface, and a drain wire connected to the conductive surface and forming a capacitive current loop with respect to the source.

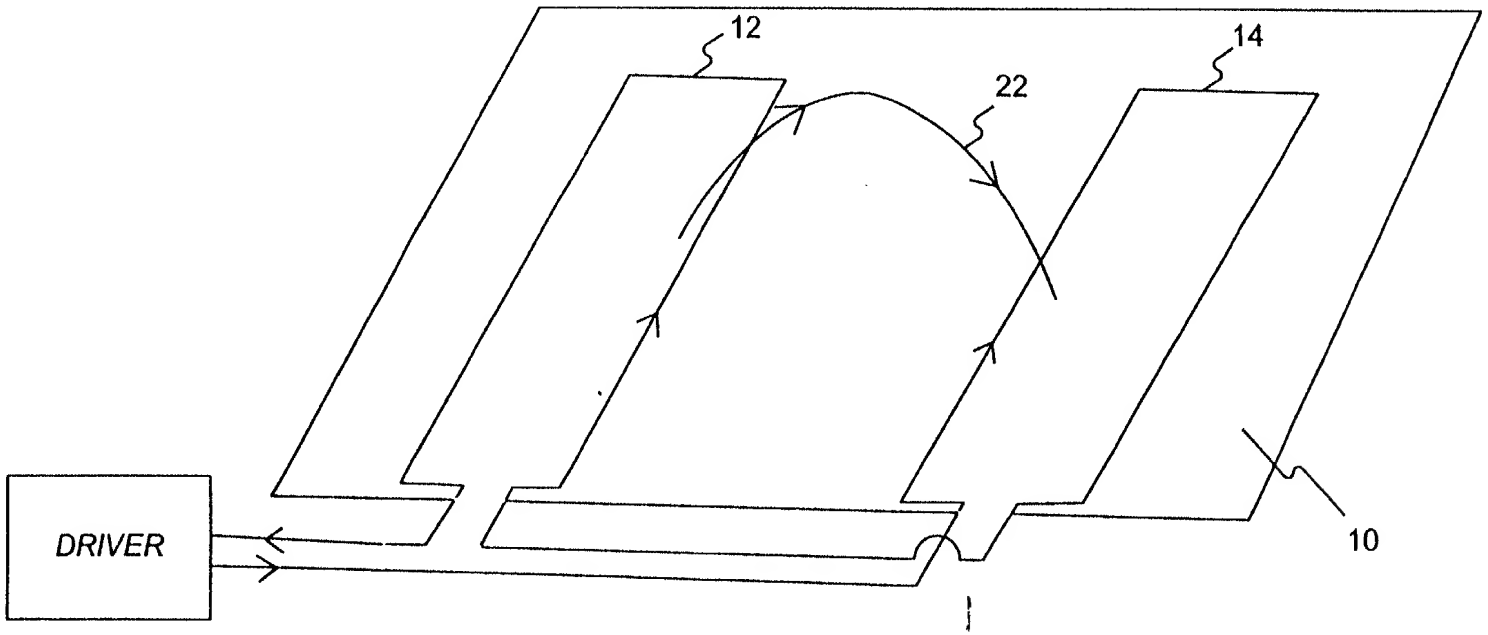

FIG. 1

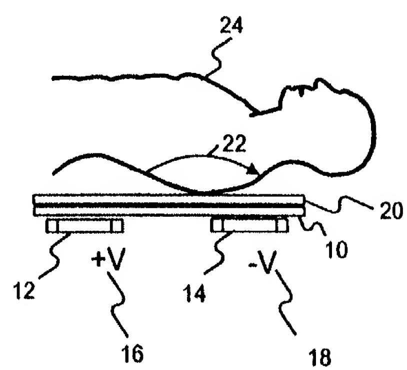

FIG. 2

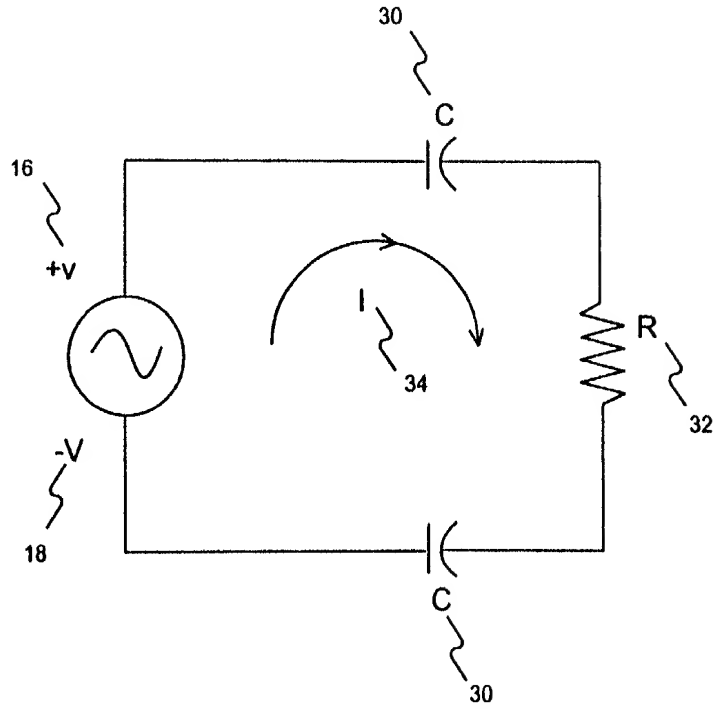

FIG. 3

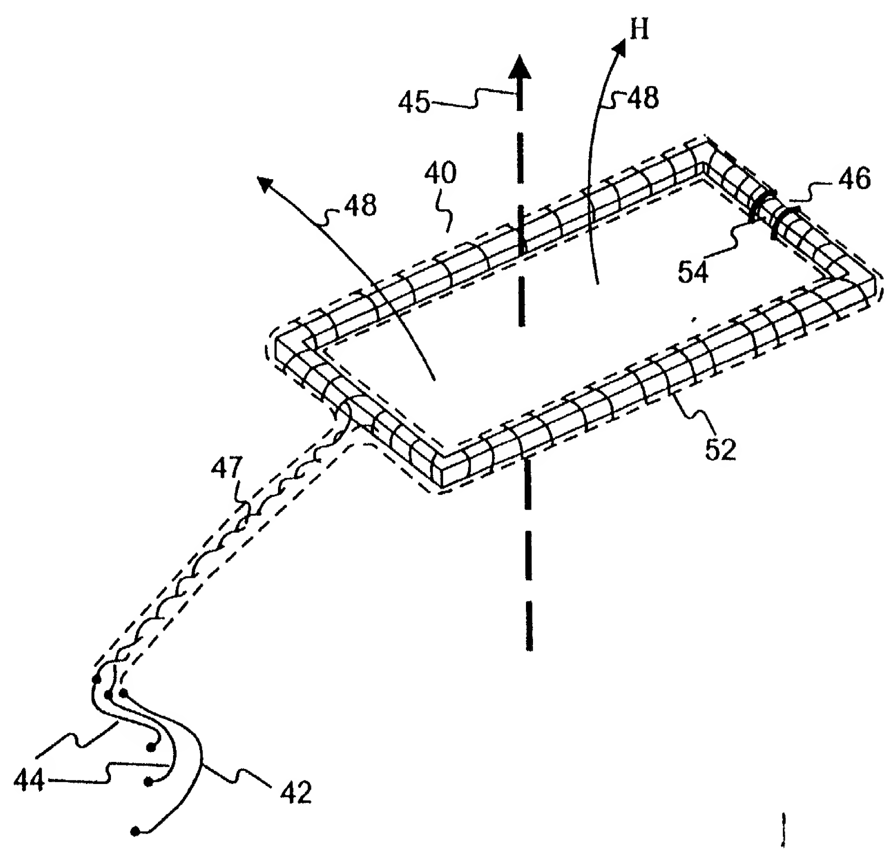

FIG. 4

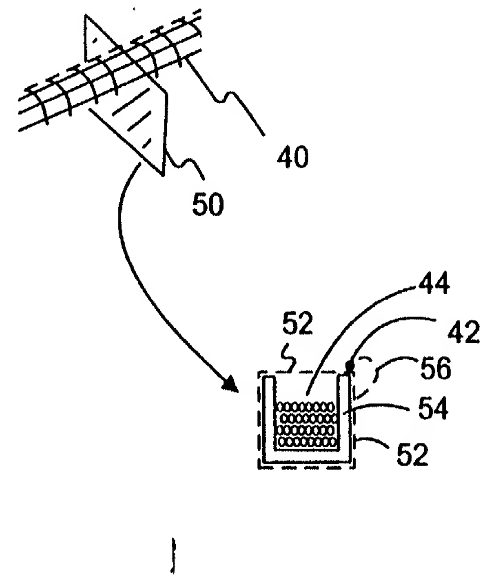

FIG. 5

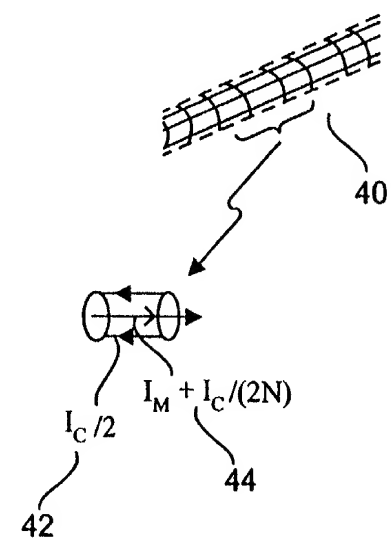

FIG. 6

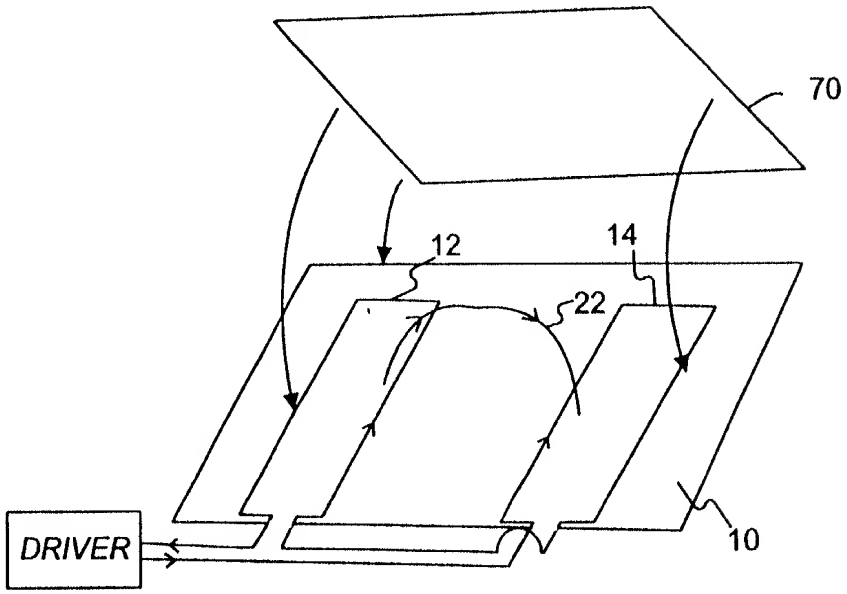

FIG. 7

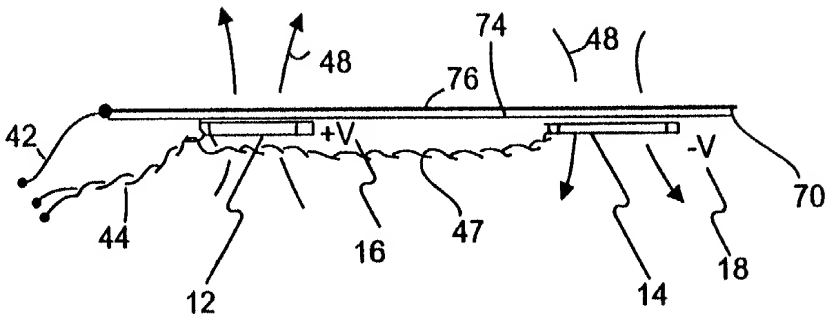

FIG. 8

Docket No.
56300- (MRT-21)

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

PATIENT-SHIELDING AND COIL SYSTEM

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

60/161,989	October 28, 1999
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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Mark G. Lappin	**Reg. No. 26,618**	**Ronald R. Demsher**	**Reg. No. 42,478**
Elizabeth A. Levy	**Reg. No. 34,375**	**Elizabeth E. Kim**	**Reg. No. 43,334**
Debra A. Gaw	**Reg. No. 38,463**	**Scott A. Ouellette**	**Reg. No. 38,573**
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Third inventor's signature Date
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Citizenship **U.S.A.**
Post Office Address ***same as above***

Full name of fourth inventor, if any
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Full name of fifth inventor, if any
Fifth inventor's signature Date
Residence
Citizenship
Post Office Address

Full name of sixth inventor, if any
Sixth inventor's signature Date
Residence
Citizenship
Post Office Address